



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/526,597

10/03/2005

Shimon Slavin

U 015659-2

5790

140

7590

12/11/2008

LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

12/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/526,597 | Applicant(s) SLAVIN ET AL. | |
| | Examiner TAEYOON KIM | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51,52,55-58,63,67,68,70,71 and 81-105 is/are pending in the application.
- 4a) Of the above claim(s) 68,70,71 and 99-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51,52,55-58,63,67 and 81-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/15/07; 6/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 51, 52, 55-58, 63, 67, 68, 70, 71 and 81-105 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 51, 52, 55-58, 63, 67 and 81-98) in the reply filed on 11/10/2008 is acknowledged.

It is acknowledged that applicant also elected species of growth factors and double-bond containing active groups.

Claims 68, 70, 71 and 91-105 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 51, 52, 55-58, 63, 67 and 81-98 have been considered on the merits.

Information Disclosure Statement

The information disclosure statement filed 11/15/2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, particularly for JP5-55148. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 51 and its dependent claims disclose a limitation drawn to viscosity being

Art Unit: 1651

higher than 22,000 Pas. There is no proper antecedent basis for the limitation in the specification.

In addition, claim 51 discloses a limitation of “a block copolymer having more than three blocks” in line 9. There is no antecedent basis for this limitation in the specification.

Claim Objections

Claim 53 is objected to because of the following informalities: The term “morphogenetic” appears to be “morphogenic”.

In addition, the term disclosed in the parenthesis appears to stand for bone morphogenic protein (BMP) rather than bone morphogenic growth factors. It is advised to either delete the term “(BMP)” or amend the term “growth factors” to “proteins”. Appropriate correction is required.

Claims 63 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The limitation disclosed in claim 63 in regard to the viscosity is the same as claim 51, and thus, there is no further limit to the subject matter of the previous claim.

Claim 96 is objected to because of the following informalities: the term “DMB” in claim 96 appears to be a typographical error. It should be “DBM” instead. Appropriate correction is required.

Art Unit: 1651

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51, 52, 55-58, 63, 67, 82-87, 89, 90, 92, 94 and 96-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 and its dependent claims recites the limitation "the polymeric system" in 13. There is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 82 recites the broad recitation of a reverse thermogelating (RTG) polymer, and the claim also recites a random [-PEG6000-O-CO-(CH₂)₄-

Art Unit: 1651

CO-O-PPG3000-]_n poly(ether-ester) or an alternating [-PEG6000-O-CO-O-PPG3000]_n poly(ether-carbonate), which is the narrower statement of the limitation.

Claims 84 and 94 recite the broad recitation of vertebrate origin, and the claims also recite the human origin which is the narrower statement of the limitation.

Claims 86 and 96 recite the broad recitation of the range of particle size of 50 to 2500 micron, and the claims also recite the range of 250 to 500 micron which is the narrower statement of the range.

Claims 87 and 97 recite the broad recitation of the ratio between 1:1 and 20:1, and the claims also recite the range 2:1 and 9:1, and also 4:1, which is the narrower statement of the range/limitation.

Claim 89 recites the broad recitation of the one silicon-containing reactive group, and the claim also recites the one group being a mono-, di- or tri-functional group, which is the narrower statement of the limitation.

Claim 98 recites the broad recitation of the range of a ratio between BMC-DBM mixture and RTG polymer being between 5:1 to 1:5, and the claim also recites the ratio being between 3:1 and 1:2, and further 2:1, which are the narrower statement of the range.

Claims 90-92 recite the limitation "said responsive polymeric system" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claims 90-92 are dependent on claim 88, and claim 88 does not disclose any "responsive polymeric system".

Claim Rejections - 35 USC § 103

Art Unit: 1651

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51, 52, 55-58, 63, 67, 81 and 83-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough (US 2002/0132012) in view of Bentley et al. (US 2006/0239961) in further view of Maeda et al. (1998; J. Appl. Polym. Sci.).

Scarborough teaches a composition comprising bone marrow cells (BMC), demineralized bone matrix (DBM), which can be in a powder format (para. 17; claims 85 and 95), and reverse phase block copolymers (para. 5 and 17-20).

Scarborough also teach powdered bone or bone particles being in average particle size from about 0.1 to about 1.2 cm (para. 14), and thus meets the limitation of claims 86 and 96.

Art Unit: 1651

Scarborough also teaches that the composition comprises bone morphogenic proteins (BMPs) (claim 52) as well as growth factors (para. 17)(claim 81).

Scarborough does not teach the block copolymer having more than three blocks, or comprising polyethylene oxide (PEO) and polypropylene oxide (PPO) chains and the chains being connected via phosgene.

Bentley et al. teach biodegradable reverse thermal gels or poly(ether carbonate) comprising PEO $[(CH_2CH_2O)_n]$ and PPO $[(CHR^1CHR^2O)_n]$, when R^1 is H, R^2 is alkyl such as methyl (CH_3) (para. 12-19). The formula of Bentley et al.'s poly(ether carbonate) comprises more than 3 blocks as shown in the formula in para. 14.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use poly(ether carbonate) of Bentley et al. as a reverse phase block copolymer used as a carrier for bone materials.

The skilled artisan would have been motivated to make such a modification because Scarborough teaches the use of reverse phase block copolymers as a carrier of the bone composition, and the poly(ether carbonate) of Bentley et al. is such a copolymer having reverse thermo gelling capability, a person of ordinary skill in the art would recognize that the poly(ether carbonate) of Bentley et al. can be used for the carrier of bone composition. Furthermore, Bentley et al. teach that the poly(ether carbonate) can be used as an implantable gel delivery system and surgical implants (para. 84, 86, 109), and thus the poly(ether carbonate) of Bentley et al. is a suitable option to be used for the carrier of bone composition of Scarborough.

The person of ordinary skill in the art would have had a reasonable expectation

Art Unit: 1651

of success in using poly(ether carbonate) of Bentley et al. as a carrier for the bone composition comprising BMC and DBM of Scarborough.

With regard to the limitation of claim 51 drawn to the polymer capable of undergoing a condensation reaction in the presence of water resulting in an increase in the molecular weight of the polymer, or the viscosity at body temperature being higher than 22,000 Pa.s, Scarborough in view of Bentley et al. are silent about this limitation. However, since the copolymer of Bentley et al. is considered substantially similar, if not identical, to the claimed copolymer, it is expected that the poly(ether carbonate) of Bentley et al. would have the identical property as the claimed copolymer.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' copolymer differs, and if so to what extent, from the poly(ether carbonate) discussed in Bentley et al. Accordingly, it has been established that the prior art copolymer, which comprises PEO and PPO chains, and phosgene being used as a chain extender, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed copolymer that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known copolymer is not disclosed in a reference does not make the known copolymer patentable. The new copolymer possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the copolymer of the cited prior art do not possess a critical characteristic that is possessed by the claimed copolymer, would advance

Art Unit: 1651

prosecution and might permit allowance of claims to applicants' copolymer.

With regard to the limitations in claims 55-58 are drawn to the properties of the block copolymer undergoing transition in response to a triggering effect such as temperature, the poly(ether carbonate) of Bentley et al. inherently meets the limitations since Bentley et al. teach the sol-gel transition of the poly(ether carbonate) being reversible such that gel is formed at 37°C (body temperature) and it becomes a free-flowing liquid at 4°C (para. 13 and 126).

With regard to the limitation in claim 67 drawn to the polymer chains (PEO and PPO chains) being connected via phosgene, Bentley et al. teach that the oligomer having bifunctional groups at the ends can be modified by reacting with a reagent such as phosgene to form a carbonate linkage (para. 96 and 97). Thus, the phosgene is used as a linker or a chain extender for two oligomers such as PEO and PPO.

With regard to the limitation in claim 82 drawn to a reverse thermo-gelating polymer being a random $[-\text{PEG6000-O-CO}-(\text{CH}_2)_4\text{-CO-O-PPG3000-}]_n$ poly(ether-ester) or an alternating $[-\text{PEG6000-O-CO-O-PPG3000}]_n$ poly(ether-carbonate), Scarborough in view of Bentley et al. do not particularly teach the limitation. However, it would have been obvious to a person of ordinary skill in the art to try PEG6000 and PPG3000 for the formation of copolymer of Bentley et al. since Maeda et al. teach these polymers are commercially available (p.2098), and thus they are known options for the forming block copolymer of Bentley et al.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that

Art Unit: 1651

a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

With regard to the limitation drawn to the amount of BMCs (claims 83 and 93), the ratio between BMC and DBM (claims 87 and 97) or the ratio between BMC-DBM mixture and RTG polymer (claim 98), the references are silent. However, it would have been obvious to a person of ordinary skill in the art to optimize the number of BMCs or the ratio of BMC and DBM to obtain optimal results from the using of the composition of Scarborough in view of Bentley et al. This is because a person of ordinary skill in the art would recognize that the amount of BMCs, the ratio between BMC and DBM or the ratio between BMC-DBM mixture and RTG polymer is a result-effective variable. The variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ

Art Unit: 1651

233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the :references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

With regard to the limitations drawn to the origin of DBM (claims 84 and 94), although Scarborough in view of Bentley et al. do not particularly teach the limitations, it would have been obvious to a person of ordinary skill in the art to use human BMCs since the composition is used for treating osteoporosis in vertebrate animals (para. 6

Art Unit: 1651

and 11).

With regard to the limitation of claim 89 drawn to the polymer having silicon-containing reactive group, Scarborough teaches that liquid silicone such as polymethyl siloxane and poly(dimethyl siloxane) and polyalkyl arylsiloxane can be a carrier for the compound comprising BMC and DBM (para. 20 and 26).

With regard to the limitation of claim 90 drawn to the polymer being a linear, Bentley et al. teach that the poly(ether carbonate) is typically a linear polymer (para. 65).

With regard to the limitation of claim 91 drawn to the polymer further comprising additional reactive groups such as double bond-containing reactive groups, Bentley et al. teach reactive groups can be alkenyl (double bond containing group) (para. 62).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 51, 52, 55-58, 63, 67, 81-90 and 92-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarborough (US 2002/0132012) in view of Cohn et al. (2003; J. Mat. Sci.).

Scarborough teaches a composition comprising bone marrow cells, demineralized bone matrix (DBM), and reverse phase block copolymers (para. 5 and 17-20).

Scarborough teaches a composition comprising bone marrow cells (BMC), demineralized bone matrix (DBM), which can be in a powder format (para. 17; claims 85

Art Unit: 1651

and 95), and reverse phase block copolymers (para. 5 and 17-20).

Scarborough also teaches powdered bone or bone particles being in average particle size from about 0.1 to about 1.2 cm (para. 14), and thus meets the limitation of claims 86 and 96.

Scarborough also teaches that the composition comprises bone morphogenic proteins (BMPs) (claim 52) as well as growth factors (para. 17)(claim 81).

Scarborough does not teach the block copolymer having more than three blocks, or comprising polyethylene oxide (PEO) and polypropylene oxide (PPO) chains and the chains being connected via phosgene.

Cohn et al. teach a reverse thermoresponsive injectable poly(ether carbonate)s comprising alternating [PEG6000-COO-PPG3000]_n block, which is linked via phosgene (see entire document).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use poly(PEG6000-COO-PPG3000) poly(ether carbonate) of Cohn et al. as a reverse phase block copolymer used as a carrier for bone materials.

The skilled artisan would have been motivated to make such a modification because Scarborough teaches the use of reverse phase block copolymers as a carrier of the bone composition, and the poly(ether carbonate) of Cohn et al. is such a copolymer having reverse thermo gelling capability, a person of ordinary skill in the art would recognize that the poly(ether carbonate) of Cohn et al. can be used for the carrier of bone composition. Cohn et al. teach that the poly(ether carbonate) can replace the

Art Unit: 1651

function of Pluronics or poloxamers (see introduction), which is well known in the art as a carrier for bone composition according to Scarborough (para. 20), and thus the poly(ether carbonate) of Cohn et al. is a suitable option to be used for the carrier of bone composition of Scarborough.

The person of ordinary skill in the art would have had a reasonable expectation of success in using poly(ether carbonate) of Cohn et al. as a carrier for the bone composition comprising BMC and DBM of Scarborough.

With regard to the properties of poly(ether carbonate), Cohn et al. teach that the poly(ether carbonate) has a reverse thermoreactive gelling property having a viscosity between 25,000 and 150,000 Pa.s (abstract) at 37°C (body temperature).

With regard to the limitations in claims 55-58 are drawn to the properties of the block copolymer, the poly(ether carbonate) of Cohn et al. inherently meets the limitations of undergoing transition in response to temperature at a body site (37°C).

With regard to the limitation drawn to the amount of BMCs (claims 83 and 93), the ratio between BMC and DBM (claims 87 and 97) or the ratio between BMC-DBM mixture and RTG polymer (claim 98), the references are silent. However, it would have been obvious to a person of ordinary skill in the art to optimize the number of BMCs or the ratio of BMC and DBM to obtain optimal results from the using of the composition of Scarborough in view of Bentley et al. This is because a person of ordinary skill in the art would recognize that the amount of BMCs, the ratio between BMC and DBM or the ratio between BMC-DBM mixture and RTG polymer is a result-effective variable. The variables would be routinely optimized by one of ordinary skill in the art in practicing the

Art Unit: 1651

invention disclosed by those references. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the :references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of

Art Unit: 1651

evidence to the contrary.

With regard to the limitations drawn to the origin of DBM (claims 84 and 94), although Scarborough in view of Cohn et al. do not particularly teach the limitations, it would have been obvious to a person of ordinary skill in the art to use human BMCs since the composition is used for treating osteoporosis in vertebrate animals (para. 6 and 11).

With regard to the limitation of claim 89 drawn to the polymer having silicon-containing reactive group, Scarborough teaches that liquid silicone such as polymethyl siloxane and poly(dimethyl siloxane) and polyalkyl arylsiloxane can be a carrier for the compound comprising BMC and DBM (para. 20 and 26).

With regard to the limitation of claim 90 drawn to the polymer being a linear, although Scarborough in view of Cohn et al. is silent in the limitation, it would be an inherent property of poly(ether carbonate) of alternating PEG-PPG copolymer as taught by Cohn et al. being a linear polymer.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Art Unit: 1651

supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651